## REMARKS

Applicants appreciate the detailed examination evidenced by the Action. Applicants wish to thank the Examiner for the telephone interview on August 9, 2006. Issues raised in the telephone interview are address herein. To the extent necessary, this response shall fulfill any requirements for an Interview Summary pursuant to MPEP §713.04.

In response to the Action, Independent Claims 1, 25, 54, and 66 have been amended to recite that the pushing pulse is delivered for between about 0.025 and 10 milliseconds and that the plurality of tracking signals comprise parallel beam formed signals. Independent Claims 28, 47, 65, 75, and 82 have been amended to recite that the detected mechanical property comprises a dynamic response to radiation force excitation.

Applicants request that claim rejections under nonstatutory double patenting and under §§ 112, 101 and 102/103 be withdrawn for at least the reasons discussed below.

### Section 112 Rejections

As noted above, independent Claims 1, 25, 54, and 66 have been amended to recite that the plurality of tracking signals comprise parallel beam formed signals, as originally recited in Claim 2. Applicants submit that, in view of the above amendments, Claims 1, 3-27, 54, 56-57, 59-63, 66-68, and 70-74 satisfy the requirements of § 112 and request that the rejections under § 112 be withdrawn.

### Section 101 Rejection

Claims 1-2, 10-13, 23-25, 27-28, 35-44, 47, 54-55, 64, 66-67, 75 and 81-82 stand rejected under 35 U.S.C. § 101. Specifically, the Action states that "the reception of signals irrespective of the application specifically involved is per se an abstract result" and concludes that various claims are "deficient regarding the recitation of a statutory result." *the Action, page 5*. Applicants traverse the rejection because the claims recite results which are useful, tangible, and concrete, fully in compliance with U.S. case law. Furthermore, the claims fully comply with the New Guidelines set out by the USPTO on October 26, 2005[1] (the "USPTO New Guidelines").

For example, Claim 1 recites an ultrasound method that includes, *inter alia*, delivering a pushing pulse from an ultrasound transducer array to a target region within a medium to displace the target region to a displaced position, delivering a tracking pulse and receiving a plurality of tracking signals from locations in the target region, each tracking signal being responsive to the tracking pulse. The utility of ultrasound techniques, for example, for imaging and tissue characterization is well-known. More specifically, as discussed in the application, ultrasound methods can be used to characterize and/or image regions of increased stiffness. *See paragraph 21.* For example, the displacement magnitude of tissue responsive to a force is inversely proportional to local tissue stiffness. *See paragraph 36.* In particular embodiments, the relative mechanical properties, including displacement and/or stiffness, of diseased vessel tissue during various points in the cardiac cycle or at various points within different vessel wall layers may be used to measure blood vessel health. *See paragraph 27 and, e.g., Claims 28 and 47.* Accordingly, delivering pushing pulses and tracking pulses and receiving the tracking signals or evaluating the relative mechanical properties of vessel tissue and/or cardiac tissue clearly produces a useful, tangible and concrete result.

In comparison, the decision in *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998), held that determining a price of a share of stock was concrete, useful, and tangible. Applicant respectfully maintains that the claimed ultrasound and blood vessel evaluation related inventions are at least as concrete, useful, and tangible as determining the price of a share as described in *State Street.*

Accordingly, Applicant requests the withdrawal of the § 101 rejections for at least the reasons described above.

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[1] See http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

## Double Patenting Rejections

Claims 1-68 and 70-88 stand rejected under the judicially created doctrine of non-statutory double patenting. *the Action, pages 6-10*. Applicant is submitting concurrently herewith a properly executed Terminal Disclaimer in compliance with 37 C.F.R. 1.321(c) to overcome the nonstatutory double patenting rejection. The filing of the Terminal Disclaimer is being done to expedite allowance of the present application and it is not to be considered an admission that the pending claims are not patentably distinct from the various patents cited in the Action.

## Section 102/103 Rejections

### Independent Claims 1, 25, 54 and 66

Independent Claims 1, 25, 54, and 66 have been amended to incorporate the recitation of Claim 2 and to recite that the pushing pulse is between about 0.025 and about 10 milliseconds (*See* Claim 11 and page 9 of the application). Claims 1, 25, 54 and 66 recite that the pushing pulse is delivered for between about 0.025 and 10 milliseconds and that the plurality of tracking signals comprise parallel beam formed signals. For example, Claim 1 recites an ultrasound method including:

> delivering a pushing pulse for between about 0.025 to about 10 milliseconds from an ultrasound transducer array having a plurality of elements to a target region within a medium to displace the target region to a displaced position;
>
> delivering a tracking pulse from the ultrasound transducer array to the target region; and
>
> receiving a plurality of tracking signals from locations in the target region, each tracking signal being responsive to the tracking pulse, wherein the plurality of tracking signals comprise parallel beam formed signals.

The Action rejects the subject matter of Claims 2 and 11 (which recites delivering a pushing pulse for between about 0.025 to about 0.5 milliseconds) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,270,459 Konofagou et al (Konofagou) alone or further in view of Walker (J. Acoust. Soc. Am. 105(4) April 1999) (Walker) alone or further in collective view of U.S. Patent No. 6,352,507 to Torp et al. (Torp), U.S. Patent No. 6,221,020 to Lysansky et al. (Lysansky), and Geiman et al. (Phys. Med. Biol. 45 (2000) (Geiman).

As noted in the Action, Konofagou uses the array itself to physically push the tissue from outside the body. *See the Action, pages 13-14.* The Action relies on Walker as disclosing "pushing" that originates in the ultrasound array proper. *See the Action, page 17.*

Walker discusses the application of acoustic radiation force using acoustic fields applied for 10 seconds (*See* Walker, Figures 1-6), and Walker does not teach or suggest pushing pulses delivered from an ultrasound transducer array for between about 0.025 to about 10 milliseconds as recited in Claims 1, 25, 54 and 66.

Applicants submit that the techniques discusses in Walker may have certain disadvantages compared to embodiments of the present invention. For example, Walker concludes that his results indicate that radiation force imaging may be easily applied to the vitreous, but may be less practical for stiffer tissues such as the breast and liver and makes no mention of using radiation force imaging in tissue such as blood vessel tissue. The claimed shorter duration pushing pulses of about 0.025 to 10 milliseconds can also provide for multiple applications of radiation force in more rapid succession. For example, Claim 25 recites "repeating sequentially the delivering a first tracking pulse, receiving a first tracking signal, delivering a pushing pulse, delivering a second tracking pulse, and receiving a second tracking signal to provide a series of cycles, the pushing pulses being delivered to different target regions during the series of cycles providing a plurality of displaced positions."

Accordingly, Konofagou and Walker do not teach or suggest pushing pulses between 0.025 to 10 milliseconds as recited in Claims 1, 25, 54 and 66. It is Applicants' understanding that Torp, Lysansky, and Geiman are relied on by the Action as proposing parallel processing for various elastographic characterizations. Therefore, Torp, Lysansky and Geiman do not cure the deficiencies of Konofagou and Walker.

For at least these reasons, Applications submit that Claims 1, 25, 54 and 66 and Claims 3-10, 12-24, 26-27, 56-63 and 67-74 depending therefrom are patentable over the cited references and Applicants request that the rejections under §§ 102/103 be withdrawn.

**Claims 28, 47, 65, 75 and 82**

Independent Claims 28, 47, 65, 75 and 82 have been amended to incorporate the recitations of Claim 35. In particular, Claims 28, 47, 65, 75, and 82 recite that the detected mechanical property comprises a dynamic response to radiation force excitation. For example, Claim 28 recites a method for evaluating a blood vessel and/or cardiac tissue in a subject including:

> detecting a mechanical property of a vessel wall and/or cardiac tissue to provide at least first and second values associated with the mechanical property at at least two timing points during a cardiac cycle of the subject; and
>
> comparing the first and second values, wherein the detected mechanical property comprises a dynamic response to radiation force excitation.

The Action rejects the subject matter of Claim 35 under 35 U.S.C. § 103(a) as being unpatentable over Konofagou alone or further in view of Walker alone or further in view of Torp, Lysansky, Geiman, and further in view of U.S. Patent NO. 6,165,128 to Cespedes et al. (Cespedes) and de Korte (Phys. Med. Biol. 45 (2000) pp. 1465-1475) (de Korte).

As noted above, the Action concedes that Konofagou does not use acoustic radiation force as a push mechanism. *See the Action, page 14.* The Action characterizes Walker as establishing "utility for acoustic radiation force as a push mechanism advance over mechanical compression to be provided by the ultrasound array itself for a variety of quasi-static tissue types, *i.e.*, liver/breast vitreous. *See the Action, pages 14-15.* The Action further states that de Korte and Cespedes suggest that vascular tissue can be treated "like any other tissue for mechanical property evaluation," and concludes that "vascular external study using radiation force-induced (ultrasound array pushing) elastography, and in association with parallel processing, would have been a known variant in consideration of this art." *See the Action, page 15.* The Action further cites Torp as proposing cardiac strain imaging.

However, de Korte, Cespedes and Torp each rely on movement of the cardiac or blood vessel tissue to deform the tissue. de Korte and Cespedes obtain images of an artery at different intraluminal pressures. *See* Cespedes, col. 5, line 65- col. 6, line 5 and de Korte, Abstract, second paragraph. In fact, Cespedes discusses that in other areas that lack the pressure source provided by the pulsation of blood and the acoustic contact provided by blood, a fluid-filled balloon should be utilized to apply the probing deformation of the tissues and acoustic coupling. *See* Cespedes col, 7, lines 36-41. Accordingly, Applicants submit that de Korte and Cespedes teach that the natural change in intraluminal pressures during the cardiac cycle can be used as an excitation force. Torp relates strain rate or strain values to movement during the cardiac cycle. *See* Torp, col. 5, line 67 – col. 6, line 2. As such, de Korte, Cespedes and Torp teach away from using a dynamic response to radiation force excitation to detect mechanical properties of a blood vessel and/or cardiac tissue as recited in Claims 28, 47, 65, 75 and 82.

For at least these reasons, Applications submit that Claims 28, 47, 65, 75 and 82 are patentable over the cited references. Claims 29-34, 36-46, 48-53, 76-81 and 83-88 are patentable at least per the patentability of the claims from which they depend and Applicants request that the rejections under §§ 102/103 be withdrawn.

## CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any small matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

Laura M. Kelley
Registration No.: 48,441

**USPTO Customer No. 20792**
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

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Carey Gregory